State of California

Unified California Environmental Protection Agency

Policy and Guiding Principles

For External Scientific Peer Review

March 13, 1998
(Revision A)

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I. INTRODUCTION

A. Goals

The California Environmental Protection Agency (Cal/EPA) views scientific peer review as the appropriate mechanism for ensuring that regulatory decisions and initiatives are based on sound science. Scientific peer review helps strengthen regulatory activities, establishes credibility with stakeholders, and ensures that Cal/EPA manages public resources effectively to meet its mission of protecting public health and the environment. In fact, when creating the Cal/EPA, Governor Wilson noted that regulatory decisions "must be based on rigorous and internally consistent science, at the level widely recognized to be the best available" (Governor's "Reorganization Plan Number One," April 16, 1991).

This document discusses the Cal/EPA's policy and guiding principles regarding how the various Boards, Departments, and Offices (BDO)[1] incorporate external scientific peer review into their regulatory decisions and related initiatives. The policy and guiding principles cover both the legislative mandate (Chapter 295, Statutes of 1997, Sher, thereafter referred to as Sher 1320) for external peer review of the scientific portion of rules establishing a regulatory level, standard or other requirement for the protection of public health in the environment, as well as Cal/EPA's directive calling for external peer review of the scientific basis of program initiatives. It provides for more consistency and uniformity across the various BDOs in terms of scientific peer review.

The Cal/EPA Peer Review Working Group (PRWG) developed and reviewed this document; the Working Group includes members from all of the Cal/EPA BDOs.

B. Background

The Cal/EPA and its constituent BDOs have numerous responsibilities for identifying and managing risks to public health and the environment. Over the last several years, the Cal/EPA BDOs have developed a number of different processes to carry out these responsibilities. Through these processes, scientists and other experts have been involved in developing and reviewing the information and data underlying the regulatory decisions of the BDOs.

In directing these efforts, Cal/EPA has worked to integrate and organize the peer review processes, to establish a hierarchy of levels for peer review, and to create a process for regularly evaluating the effectiveness of a BDOs peer review and involvement program. These efforts have and will continue to enhance the credibility of Cal/EPA's regulatory programs and other public initiatives.

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[1] The Cal/EPA BDOs include the Air Resources Board, Department of Pesticide Regulation, Department of Toxic Substances Control, Integrated Waste Management Board, Office of Environmental Health Hazard Assessment, and State Water Resources Control Board.

Specifically, the following state and federal work groups or committees have identified peer review as an important aspect of agency decision-making:

> Risk Assessment Advisory Committee (RAAC),
> Commission on Risk Assessment and Risk Management (Commission), and
> U.S. Environmental Protection Agency (US EPA) Office of Prevention, Pesticides and Toxic Substances (OPPTS)

In a recent report to Cal/EPA, the RAAC highlighted the importance of external peer review of regulatory activities as an important function that lends credibility to risk assessment while providing a mechanism for external input to the process.[2] The Committee recommended that:

> Cal/EPA should develop a formalized policy for internal and external peer review of its activities. It should identify goals and objectives of the program and Cal/EPA should design a program to meet its objectives.[3]

Further, the Governor's Executive Order W-137-96 requires Cal/EPA and its constitute BDOs to draft plans to implement recommendations of the RAAC.

Recently, with the passage of Sher 1320, the Cal/EPA was given impetus to integrate, organize, and augment its ongoing scientific peer review programs. Sher 1320 requires that no Cal/EPA BDO:

> ... shall take any action to adopt the final version of a rule ... [without submitting] ... the scientific portions of the proposed rule, along with a statement of the scientific findings, conclusions, and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer entity for its evaluation.

In addition to these state level calls for a specific guidance by Cal/EPA on peer review, recent activity on the national level has also focused on the importance of peer review in the regulatory process. The Commission noted that independent peer review plays a critical role in formulating scientific initiatives. As such, peer review is an important and effective mechanism for evaluating the accuracy or validity of technical data, observations, and interpretations, and scientific aspects of regulatory decisions and initiatives. The Commission further emphasized two important elements for effective peer review.

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[2] California Environmental Protection Agency. *A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines*, October 1996. Chapter 2. Section E.1.p. 2-24. Sacramento, California.

3 Ibid

> Peer review should provide balanced, independent views. When used well, peer review can serve as a system of checks and balances for the technical aspects of the regulatory process.
>
> Peer review should be conducted not simply to seek legitimacy for Agency decisions and positions, but to improve their quality.[4]

The US EPA OPPTS in its document entitled Standard Operating Procedures for Peer Review of Major Scientific and Technical Documents underscored the need for peer review as follows:

> The purpose [and benefit] of peer review is to uncover any technical problems or unresolved issues for use in revising a preliminary product so that the final work product will reflect sound technical information and analyses. It should be noted that peer review is a process for enhancing the scientific or technical work product.[5]

In consideration of these state and national recommendations, Cal/EPA and its constituent BDOs are committed to creating a system for peer review. Specifically, this document provides general principles and specific direction regarding the creation of formal external scientific peer review by the Cal/EPA BDOs to comply with Sher 1320.

II. DEFINING CONCEPTS ASSOCIATED WITH SCIENTIFIC PEER REVIEW

This section defines a number of concepts related to scientific peer review. This discussion will help Cal/EPA BDOs comply with Sher 1320, meet RAAC recommendations for peer review, and establish other types of peer involvement.

A. External Scientific Peer Review

As required by Sher 1320, external scientific peer review means review by an independent scientific expert of the work product or products (or portions thereof) that constitute the scientific basis for a rule "... establishing a regulatory level, standard, or other requirement for the protection of public health or the environment." Sher 1320 defines "scientific basis" as "the foundations of a rule that are premised upon, or derived from empirical data or other scientific findings, conclusions, or assumptions establishing a regulatory level, standard, or other requirement for the protection of public health or the environment." Under Sher 1320, "rule" includes any regulation as defined in section 11342 of the Government Code and any policy adopted by the State Water Resources Control Board under the Porter-Cologne Water Quality Control Act (Division 7, commencing with section 13000 of the Water Code) that has the effect of a regulation.

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4 *Risk Assessment and Risk Management in Regulatory Decision-Making* (1996), Section 5.5, p. 82.

5 Office of Prevention, Pesticide and Toxic Substances (OPPTS). *Standard Operating Procedures for Peer Review of Major Scientific and Technical Documents.* October 1995. page 1.

To meet these requirements, the Secretary of Cal/EPA will be responsible for all peer review activities. As such, the Secretary's Office will authorize the Cal/EPA PRWG as the panel for reviewing and approving any proposed peer review panel that performs multi-media or cross-media reviews (see pages 2 and 17, B1), as well as consolidating information on all reviews.

Peer review is an objective, critical review of a draft Agency scientific work product, typically by independent scientific experts. Although peer review can occur at several discrete points during the peer involvement process, it is typically characterized by a one-time interaction or a limited number of interactions by the peer reviewer(s). In these instances, peer review is part of the culmination of the work product development, ensuring that the final product is scientifically sound. Peer review can also occur during the early stages of a project or methods selection.

B. Peer Review in its Broader Function

Peer involvement can include expert participation in the development or review of the scientific portions of a work product supporting Agency initiatives. The purpose of this expert participation generally is to uncover any technical problems or unresolved scientific issues in a scientific work product so that the final work product will reflect sound scientific information and analyses. It should be noted that all peer involvement processes are intended to enhance the scientific work product.

As a part of peer involvement, peer input requires an open exchange of data, insights, and ideas between the agency staff responsible for developing of a work product and the experts consulted. Peer input is characterized by a continued and iterative interaction with the expert(s) during the early stages of peer involvement.

The subject matter experts who participate in a peer review process can be expected to undertake one of three related but different roles. First, they may work as paid or unpaid consultants with a significant role as author or advisor in developing a work product Second, Cal/EPA BDOs may ask independent experts to provide peer input by participating in early developmental reviews or discussions of unfinished work products. Third, experts may be asked to serve as peer reviewers, providing critical evaluation and comments on work products nearing completion. This third role will commonly be used for Cal/EPA□s external peer review process.

1. Formal vs Informal Peer Review

While other types of peer involvement may be carried out without formalized procedures, Cal/EPA BDOs should develop and implement official, written guidelines relating to external scientific peer review. This formality helps ensure the transparency of agency regulatory actions and enhance the credibility of agency decisions. Guidelines for external scientific peer review should address the basic aspects of the process such as which agency initiatives, risk assessments, regulatory options, or decisions will be subject to peer review. The Guidelines should discuss how the BDO will determine the level of peer review for a work product or initiative. The administrative features, such as how potential peer reviewers are recommended to the President of the University of California and how to consider the outcomes of peer reviews, should be discussed.[6]

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6 Policy Statement on Peer Review and Peer Involvement At The U.S. Environmental Protection Agency, June 7, 1994.

2. Peer Review vs. Public Comment

External scientific peer review and public comment are not synonymous. Public comment is open to all issues, whereas the peer review process considers only the scientific issues. Public commentators usually include a broad array of people with an interest in the technical analysis or the regulatory decision; some are scientific experts, some are experts in other areas, and some are interested non-experts. The critical distinction is that public comment does not necessarily draw the kind of independent, expert information and analyses expected from the peer review process. Cal/EPA expects that, in general, external peer review occurs prior to release of a work product for public comment.[7]

C. Defining an Expert

In the context of peer review, an expert is someone who has demonstrated expertise in the subject matter required for the input or review function. For many agency decisions, a multi-disciplinary group of experts is often necessary for a full and complete peer review. The group will include an expert who corresponds to all the disciplines in the work project or initiative. For example, a risk assessment that relies on both animal and human data may often require experts in both areas for a complete review.

An independent expert is one who has not been associated with the generation of the specific work product either directly by substantial contribution to its development or indirectly by consultation during the development of the specific product. To be independent, an expert should be free from bias of any kind as to the issues under review. Such independence is necessary for objective, fair, and responsible evaluation of the work product under review.

For reviews required by Sher 1320, no person may serve as an external scientific peer reviewer for the scientific portion or basis of a rule if he or she participated in the development of the rule. The peer reviewer may not be employed by Cal/EPA or its BDOs except in the capacity as an independent external peer reviewer. For purposes of this prohibition, a member of one of Cal/EPA's or a BDO's scientific advisory panel is not an employee of the agency.

III. PLANNING FOR EXTERNAL SCIENTIFIC PEER REVIEW

This section discusses the elements that BDOs will need to consider when planning a work project or initiative for external scientific peer review. Specifically, the section discusses the types of work projects or initiatives that do and do not require external scientific peer review, along with the necessary level of review.

A. Work Projects Requiring External Scientific Peer Review

Sher 1320 requires Cal/EPA BDOs to conduct an external scientific peer review of the scientific basis for any rule, as defined, establishing a regulatory level, standard, or other requirement for the protection of public health or the environment.

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7 As required by state law, the Office of Environmental Health Hazard Assessment (OEHHA) currently does, and will continue to, allow public comment on certain work products prior to external peer review by the Air Resources Board's Scientific Review Panel (SRP), or OEHHA's Science Advisory Board (SAB), or as deemed appropriate to meet BDO management needs.

1. Scientific Products that Support Regulations, Standards, or Rules

Examples include the following:

a. Risk assessments that form the basis for proposed rules (including associated hazard, dose-response, and exposure analyses).

b. Scientific studies, data, experiments, and modeling results that form the basis for proposed rules.

c. Critical technical guidance documents for the regulated community.

In addition, BDOs should also consider whether the scientific basis for a specific rule, major scientific initiative, or method not subject to the mandate of Sher 1320 should nevertheless be submitted for external scientific peer review.
Work products subject to review include:

2. Products that Address Emerging or Controversial Issues, Have Significant Cross-Media Implications, or Establish a Significant Precedent

Examples include the following:

a. Application of new scientific findings in hazardous waste classification.

b. Risk assessment methods, development, and findings, e.g., impacts concerning children or new environmental chemical fate transport models that substantially modify risk outcomes.

c. A work product that supports major regulatory decisions or initiatives of major impact.

3. New Decision Criteria, Analytical Tools, or Models of Significance, or Changes in Assessment Methodologies to be Used Routinely in Risk Assessment

Examples include the following:

a. Newly developed or revised expert systems and quantitative techniques designed to help predict hazards, chemical fate, etc., from chemical structure, use, or toxicity/exposure data.

b. Significant new or revised models and other techniques designed to predict exposure, simulate transport, etc.

c. Changes or innovations in analytical measurement techniques for pollutants.

d. Decision criteria to be developed for the scientific aspects of classes of chemicals.

B. Work Projects Not Requiring External Scientific Peer Review

There are several circumstances when peer review work products do not require under SB1320. These work products include but are not limited to the following:

1. A particular work product that has been peer reviewed with a known record by a recognized expert or expert body. Additional review is not required if a new application of an adequately peer reviewed work product does not depart significantly from its scientific approach. These types of work projects would include standards developed by the U.S. EPA, which Cal/EPA adopts. This would include standards that Cal/EPA adopts from those developed by US EPA. These US EPA standards are presumed to have been sufficiently peer reviewed unless additional peer review is required by law.

2. Technical performance related to new control standards or manufacturing technologies, such as emission standards for new motor vehicles or consumer products. It is not the intent of Health & Safety Code section 57004 to review engineering data to support the technological feasibility of these standards or technologies.

3. Exploratory Analyses and Voluntary Risk Reduction Cal/EPA is involved with a number of activities that involve exploratory scientific and technical analyses. For example, BDOs may collaborate with stakeholders and members of the regulated community to characterize the hazards, uses, exposure, and risks of a substance to identify pollution prevention opportunities. In other cases, alternative chemicals or processes may be used to set priorities for additional testing or information gathering. These scientific work products would not usually require peer review until such time that they would provide the basis for regulatory initiatives.

4. Administrative standards and rules which are primarily management directives for which the underlying scientific principles, computer models, or decision tools have already been appropriately reviewed.

5. The requirement for external scientific peer review under Sher 1320 does not apply to the adoption of emergency regulations under Government Code section 11346.1(b). However, in situations where a final regulation is to be adopted to replace the emergency regulation, Sher 1320 would apply to the final regulation, under the requirements set forth in this document.

6. Permit, variance standards, and conditions set by Cal/EPA BDOs, unless they are applied through regulation (e.g., permit by rule).

Appendix A is a list of Cal/EPA work products that may require external scientific peer review under Sher 1320 and this policy. This list is not necessarily inclusive of all work products that will go through external peer review, nor will all the work products on this list always require external peer review.

C. Level of Peer Review

The level of peer review should be commensurate with the level of scientific importance and regulatory impact of the decision to be made. Each BDO has the discretion and responsibility to choose the appropriate level of peer review and is encouraged to take advantage of the Peer Review Work Group's collective experience in conducting and administering peer review. Generally, the more novel or complex the science, the greater the cost implications of the impending decision, the greater the potential for multi-media impact, or the more controversial the issue, the greater the need for an extensive and involved external peer review. Other work products may not need a large scale external peer review.

In determining the appropriate level of scientific peer review, the BDOs should consider the level of importance as part of their overall management needs as to whether the work project or initiative needs an extensive, moderate, or limited peer review. (See Appendix B, Matrix for Appropriate Level of Review.) The level of review must be determined at the time the work is planned so that peer review costs and time can be budgeted into the work plan.

1. Extensive Review

This level of review is a cornerstone of good management practice for any major initiative that has substantive scientific underpinnings. For an extensive review, the peer review group would ordinarily be a national body of experts selected in cooperation with the University of California (UC) President's Office. An extensive review is particularly needed in emerging areas of multi-media environmental protection. Initiatives that substantively cut across BDO organizational lines should have a firm scientific basis supported by extensive, external peer review. Primary examples include:

a. A work product supporting scientific initiatives of major impact.

b. A work product that has significant cross-agency, cross-media implication.

c. A work product that addresses controversial or significant emerging issues or establishes a significant precedent.

2. Moderate Review

This level of review typically would be used for a rule, establishing a regulatory limit, standard, or other requirement for the protection of public health or the environment that is based on substantive scientific information, where an extensive review is not warranted. In this case, an appropriate peer review group may include experts from the University of California, California State University, similar institutions, or be a collection of experts selected in cooperation with the UC President's Office. The primary examples include:

a. Work products that provide the scientific basis for a proposed rule as defined by Sher 1320.

b. A work product that satisfies a statutory or other legal mandate for peer review.

3. Limited Review

This level of peer review is for changes in analytical measurement methods or modifications in computer models. The appropriate peer reviewer(s) in this instance may be qualified experts from an institution (e.g., U.S. EPA, American Society of Testing Materials (ASTM), University, research institute, etc.) suggested by the Cal/EPA manager in charge of this activity. The external evaluation of these changes or modifications will provide support for agency actions based on data obtained by new measurement or modeling methods.

For example, results from peer-reviewed models used for evaluating site specific remediation will better survive legal scrutiny if challenged in court. For these reasons, it may be prudent to have the changes evaluated by external peers. At this level, obtaining the opinion of one or two experts should be sufficient. Examples of work products that should be considered for this level of review:

a. A work product that considers an innovative approach for a previously defined problem/process/methodology.

b. A work product that addresses a change in model development or analytical instrumentation.

c. A work product that establishes scientific decision criteria to be used in the regulation of a pesticide.

D. Formulate the Charge to the External Peer Reviewer

As part of the external scientific peer review process, Cal/EPA BDOs should formulate a clear, focused charge that identifies relevant issues and questions, invites comments or assistance, and presents specific issues that the BDOs expect the reviewers to address. This request signals a BDO's awareness of critical scientific issues and its receptivity to expert recommendations. The charge to peer reviewers should focus the review by specific questions, which also greatly simplify the task of collating, analyzing, and synthesizing peer review comments on a topical basis. Written responses to these questions by peer reviewers help the agency create a peer review record.

The charge should identify the scientific portion of the rule and the scientific basis for the rule. This may be all or portions of the rule itself or the documents/work products to be presented in support of the rule. In reviewing all appropriate scientific aspects of the work product, the peer reviewers may also identify other important issues.

IV. CONDUCTING EXTERNAL SCIENTIFIC PEER REVIEW

This section discusses the principles used in conducting an external scientific peer review, including identifying potential peer reviewers. (See Appendix C, External Peer Review Process.)

A. Identifying Peer Reviewers

The success and usefulness of any external scientific peer review depends on the quality of the peer review draft, the care given to the statement of the issues or "charge," the match between

the peer review draft and the form of peer review, the match between the peer review draft and the scientific/technical expertise of the reviewers, and use of peer review comments in the final product by the Cal/EPA. The Cal/EPA recognizes that to conduct external scientific peer review each of the foregoing elements requires serious attention.

An external scientific peer review panel or group, with an appropriate disciplinary mix, will often be required to provide a complete peer review of a complex work product. The make-up of such a group will depend on the time and resources available and the expertise required to treat the full range of issues/questions. Naturally, experts whose understanding of the specific scientific area(s) being evaluated are critical; nevertheless, it is also important to include other experts to completely evaluate all relevant scientific aspects of the work product. It may also be appropriate in some instances to have only a single external peer reviewer.

Ideally, peer reviewers should be free of real or perceived conflicts-of-interest or there should be a balancing of interests among peer reviewers. Should a reviewer be selected who may be perceived as having specific technical perspectives, such perspectives or potential conflicts of interest, real or perceived, must be identified and balanced to ensure credible peer review. As noted in Section II. C, an expert who provides peer input as an author, advisor, or early participant in the developmental reviews or discussion cannot be considered independent and unbiased for the given work product and should be excluded from most peer review activities. Such exclusion is required under Sher 1320.

1. Sources for Peer Reviewers

Potential peer reviewers can be identified and recommended from a number of organizations. Cal/EPA is developing a Memorandum Of Understanding and developed a Memorandum Of Agreement with the UC President's Office for the purpose of implementing the provisions of Sher 1320 and these Guidelines. The intent of the agreement with the UC President's Office is to create a mechanism for obtaining peer review expertise utilizing a rapid response task order process with the University of California system. Similar memoranda may be developed with other institutions of higher learning, including the California State University System. Specifically, Sher 1320 authorizes the following:

a. Enter into agreements between Agency, or its individual BDOs, and individual institutions and with an individual scientist recommended by the President of the University of California for the purpose of peer review;

b. Enter into an agreement with a peer review panel of highly qualified individuals with a variety of institutional affiliations. In such cases, the reviewer(s) must be approved by the Office of the President of the UC;

c. Enter into an agreement with the National Academy of Sciences; and

d. In some cases the make-up of the peer review entity is specified by statute. For example, the Health and Safety Code section 39661 provides that the Scientific Review Panel (SRP) established under Health and Safety Code section 39670 et seq. shall review the report prepared to assess the risk from and exposure to compounds that may be toxic air contaminants.

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2. Constraints in Utilizing Peer Reviewers

a. Where the external peer review entity is a multi-member panel, committee, or similar group, such as the Scientific Review Panel established under Health and Safety Code section 39670 et seq., legal counsel should be consulted to determine whether the Open Meeting Act, Government Code section 11120 et seq., applies to the actions of the panel, committee, or similar group.

b. Care must be taken to minimize the possibility for real or apparent conflicts of interest between the reviewers and the work product under review.

c. To evaluate Cal/EPA-generated studies properly, some peer reviewers may need access to confidential business information (CBI). Whenever contemplating the use of outside peer reviewers, BDO staff should determine whether the reviewers will need access to CBI. If so, the Chief Counsel of the affected BDO should be consulted on whether it is practical to obtain the consent of CBI submitters to disclose the information to peer reviewers, as well as what steps must be taken to protect CBI in such situations.

3. Agency Review

The Secretary of Cal/EPA is ultimately responsible for all peer review activities within the Agency. While many work products are media-specific and reasonably straightforward, in some cases the technical aspects of the review will cut across organizational lines, be multi-media in content, or be highly controversial. In these instances, the proposed peer review panel selections will be reviewed and approved by the Cal/EPA PRWG. The PRWG will have monthly meetings to review all peer review activities. These activities will be incorporated into a management tracking system maintained by the Secretary's Office. The PRWG is described in V.B.

B. Scheduling Peer Reviews

The peer review schedule is a critical feature of the process. The schedule must take into account the availability of a peer review quality draft work product, availability of appropriate experts, time available for using peer review comments, deadlines for the final work product, and logistical aspects of the peer review (e.g., contracting procedures).

The schedule for peer review should take into account the overall rulemaking (or other decision-making) schedule. Peer review sometimes leads to new information and analyses, or recommendations for new research that would alter the work product and thus modify the scientific/technical basis for the action. For this reason, the peer review process should usually be initiated as early as possible in the development of a proposed rule.

C. Materials to be Provided to Peer Reviewers

The materials to be reviewed by the external scientific peer reviewer(s) is the work product. For purposes of Sher 1320, a work product is a document or other instrument constituting the empirical data or other scientific finding, conclusion or assumption constituting the foundation of a rule as defined establishing a regulatory level, standard or other requirement for the protection of public health or the environment. Peer reviewers should receive these materials on a timely basis to conduct a complete review of the work product.

The individual BDOs are responsible for identifying the work product that provides the scientific basis for a proposed rule as defined, as well as the level of review which is to be consistent with the policies and guiding principles set forth in this document. As noted in Section III above, peer review should be considered for the full field of possible work products that could benefit from peer review, and the full spectrum of peer review mechanisms for each product should be considered in making this determination.

Essential documentation for each peer reviewer includes:

a. The scientific portion of the proposed rule as defined.

b. Copies of the supporting scientific materials to be peer reviewed with associated background material and supporting documents. These materials comprise the findings, conclusions and assumptions upon which the rule in based.

c. A clear charge or statement of work seeking informed comment on identified issues to properly focus the efforts of the peer reviewers and ensure that their individual efforts can be merged.

d. A schedule for review including the date by which the reviewer must submit written comments or recommendations to the BDO.

e. The format for reviewer comments. Comments must be written and submitted in a format that facilitates the BDOs and public use.

f. BDO contact person.

g. Cal/EPA BDOs shall clearly state the appropriate responsibilities of the external scientific peer reviewer(s). This includes the reviewer's duty to ensure confidentiality of the peer reviewed work product. If the peer reviewer(s) will be informed of the need for confidentiality with regard to the release of Cal/EPA products that are stamped as "DRAFT" or "DRAFT - Do Not Cite, Quote, or Release." Premature release of draft BDO products, views, or positions is inappropriate and can be damaging to the credibility of the BDO or the peer reviewer. This action may also misinform the public in cases where data released prematurely do not stand up to peer review

scrutiny. Other mechanisms to prevent the premature release of draft documents include a disclaimer that appears in a separate section at the front of the document and creating the document with watermarks clearly delineating DRAFT status (or a header or footer that states DRAFT status) on every page. In addition, in any solicitation for peer reviewers, the necessity for confidentiality and the non-release of materials, if appropriate, shall be emphasized. Reviewers should be advised that, once their comments have been officially transmitted to a Cal/EPA BDO, their comments become part of the public record. As such, the comments, including the reviewer's identify and affiliation, are disclosable under a request for public information.

Additional, useful materials that may be provided to peer reviewers include:

a. Information concerning the process the BDO is using for the peer review.

b. The name, address, and phone, fax, and/or Internet numbers of each peer reviewer working on the specific review

c. Any scientific articles not covered in 1.h from the literature that the BDO scientists deem relevant.

Peer reviewers should be given what is needed to complete their task: they should not be overburdened with excess material.

D. Evaluating Comments and Recommendations

Sher 1320 requires that:

The board, department, or office may accept the findings of the external peer review entity, in whole, or in part, and may revise the scientific portions of the proposed rule accordingly. If the board, department, or office disagrees with any aspect of the findings of the external scientific peer review entity, it shall explain, and include as a part of the rulemaking record, its basis for arriving at such a determination in the adoption of the final rule, including reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices.

As noted in Section V. below, the Peer Review Coordinator should develop documentation that clearly demonstrates acceptance of the reviewers recommendations or delineates specific technical rationale for not accepting any or all of the review body's comments and recommendations.

E. Administrative Requirements

The Peer Review Coordinator must index and maintain the external scientific peer review record as a part of the official rulemaking record or, where no rulemaking record is required, maintain an archive. Such records are considered official records of the State of California and shall be subject to the relevant BDOs "records retention policy."

All peer review comments should be carefully evaluated and used to revise work products, where appropriate. In some cases, the BDOs may choose to prepare a document that responds to each comment. In other circumstances, comments may be addressed in a more general manner. In any case, a clear record must be maintained of the peer review process employed, as well as the specific comments received. Furthermore, the product itself must include some acknowledgment of the peer review process.

V. ACCOUNTABILITY AND RESPONSIBILITY IN THE CAL/EPA

This section provides information on the responsibilities of BDO line management for individual peer reviews and PRWG for general assistance and advice.

A. Line Management

1. Decision maker(s)

   a. The BDO Director/Executive Officer is accountable for the decisions regarding the identification of scientific work products and the mechanism(s) of peer review utilized for each of the products. The Director/Executive Officer is also responsible for ensuring that the peer reviews are performed as required.

   b. Specific responsibilities of the decision maker(s) including the following:

      i. Designating a Peer Review Coordinator to organize the peer review.

      ii. Providing advice, guidance, and support to the Peer Review Coordinator in the preparation, conduct, and completion of the peer review.

      iii. Establishing a realistic peer review schedule.

      iv. Designating the stage(s) of product development where peer review is appropriate.

      v. Ensuring that the results of peer review are adequately addressed in the final work product.

2. Peer Review Coordinator

   a. The Director/Executive Officer will designate a Peer Review Coordinator. The Peer Review Coordinator shall organize and oversee the peer review for a specific work product. The Peer Review Coordinator is authorized to prepare and bring to completion the peer review. The Peer Review Coordinator will obtain the assistance and support of others within the BDO to help support the peer review.

b. Specific responsibilities of the Peer Review Coordinator include the following:

i. Coordinate the peer review of the assigned work product.

ii. Organize and facilitate the completion of the peer review following the procedures outlined in this document.

iii. Select one or more peer reviewers as appropriate. This responsibility may require identifying a pool of candidates for the external scientific peer review effort in consultation with others involved with the peer review. The pool of candidates should then be submitted to the Office of the President of the UC as necessary. The coordinator shall take steps to identify and avoid any real or perceived conflicts-of-interest on the part of peer reviewers.

iv. Advise peer reviewers of their responsibilities.

v. Act as a liaison to the external scientific peer reviewer, or review team, group or panel. In this capacity, the coordinator shall facilitate the selection of a chairperson and provide staff support as required for the reviewer, chairperson and team, group, or panel.

vi. Report peer review activities to the Director/ Executive Officer of the affected BDO and the Cal/EPA Secretary.

vii. Collect and maintain the following materials for the external scientific peer review record, including at least:

--The draft work product submitted for peer review;

--Materials and information given to the peer reviewer(s);

--Comments, information, and materials received from the peer reviewer(s);

--Information about the peer reviewer(s) (e.g., names, affiliations, etc.);

--Any logistical information (e.g., times; locations; duration, etc.);

--The final work product.

B. California Environmental Protection Agency Peer Review Working Group

1. The PRWG will review and approve proposed peer review panels which perform multi-media or cross-agency reviews.

2. The PRWG will organize a quarterly review of the Cal/EPA's expected work products for the next fiscal year that will be subject to peer review. Where appropriate, this process should be integrated with the annual Rulemaking Calendar development process.

3. The PRWG will organize an annual review to assess the function of this policy in practice and to recommend changes

4. The PRWG will consist of one member from each BDO, as appointed by the BDO management. Each member will serve one year. The PRWG will be chaired by the Deputy Secretary for Science and Technology.

C. Legal Advice

The staff and management of Cal/EPA BDOs should continue to consult with their Offices of the Chief Counsel for legal advice or referral.

D. Budget

The Cal/EPA budget planning process for each fiscal year is the appropriate forum to ensure that peer review-related activities are appropriately budgeted and that sufficient resources will be available to effect a completed peer review.

The planning process articulates priority activities for the coming year and provides opportunities for periodic evaluation of project status, including opportunities for redirecting program priorities. The planning process facilitates development of project plans for priority projects, including identification of scientific products necessary to complete priority activities.

The project planning process provides a natural forum for discussing the nature of scientific products that will be developed to support various projects. This forum provides an opportunity to discuss the mechanism of peer involvement and/or peer review needed and how these peer activities will be achieved. Discussing the scope of peer review during the planing process provides the added benefit of ensuring that timing and resource requirements associated with peer review are included in the planning process and highlighted for senior management attention.

VI. REFERENCES

April 16, 1991. "Governor's Reorganization Plan Number One."

Risk Assessment Advisory Committee. October 1996. *A Review of California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines.*

December 10, 1996. "Governor's Executive Order W-137-96."

Commission on Risk Assessment and Risk Management. 1996. *Risk Assessment and Risk Management in Regulatory Decision-Making.* Section 5.5.

US EPA Office of Prevention, Pesticides, and Toxic Substances. October 1995. *Standard Operating Procedures for Peer Review of Major Scientific and Technical Documents.*

Appendix A

CAL/EPA WORK PRODUCTS SUBJECT TO
EXTERNAL PEER REVIEW UNDER SHER 1320*
(Chapter 245, Statutes of 1997, Sher)

Board, Department, Office	Work Product	External Peer Review
Air Resources Control Board	Ambient Air Quality Standards (Stats. 1978, c. 429)	See Recommendations on Criteria Pollutants, below under OEHHA
	Exposure Assessment for Toxic Air Contaminants (H&SC Section 39650)	Science Review Panel (H&SC 39670)
Department of Pesticide Regulation	Risk Characterization Documents	US EPA
	Exposure Assessment Documents	US EPA
	Risk Assessments for Toxic Air Contaminants	Science Review Panel (H&SC 39670)
	Formal Departmental Reports that form the Scientific Basis for a Regulation	Independent Review
Department of Toxic Substances Control	Formal Departmental Reports that form the Scientific Basis for a Regulation	National Academy of Sciences
	Scientific Guidance Documents	Independent Review
Integrated Waste Management Board	Scientific Testing Documents	Independent Review
	Formal Board documents that form the basis of regulations containing prescriptive requirements	Independent Review

Board, Department, Office	Work Product	External Peer Review
Office of Environmental Health Hazard Assessment	Risk Assessments for Toxic Air Contaminants	Science Review Panel (H&SC 39670)
	Toxic Air Hot Spots Guidelines (SB 1731)	Science Review Panel (H&SC 39670)
	Hazard Identification Documents	Science Advisory Board
	Recommendations on Criteria Air Pollutants	Air Quality Advisory Committee
	Public Health Goals	Independent Review
	No Significant Risk Levels	Independent Review
	Maximum Allowable Daily Levels	Independent Review
	Chemical, Site or Process Specific Risk Assessments to be Used by Other Boards or Departments	Independent Review
	Chemical, Site or Process Specific Risk Assessments that are of Specific Concern to the Public	Independent Review
Regional Water Quality Control Boards	Regional Water Quality Control Plans, Policies, Guidelines, and Regulations or Amendments	Independent Review
State Water Resources Control Board	Statewide and Regional Water Quality Control Plans, Policies, Guidelines, and Regulations or Amendments	Independent Review

* This list was produced on the basis of a survey of rules and supporting work products currently used by the identified BDOs and is not necessarily inclusive of all work products that will be identified for external peer review nor will all the work products on this list always require external peer review.

Appendix B

CAL/EPA EXTERNAL SCIENTIFIC PEER REVIEW MATRIX FOR APPROPRIATE LEVEL OF REVIEW*

LEVEL	NATURE OF ISSUE	EXAMPLE PRODUCTS	TYPE OF PANEL
EXTENSIVE	-SIGNIFICANT CROSS-AGENCY IMPACTS -CONTROVERSIAL AND EMERGING ISSUES -SIGNIFICANT PRECEDENT	-NEW HAZARDOUS WASTE CLASSIFICATIONS -MULTI-MEDIA IMPACTS OF SIGNIFICANT MAGNITUDE -INITIATIVES IN WHICH SCIENTIFIC FINDINGS ARE AT ODDS WITH PUBLIC RISK PERCEPTION	-NATIONAL RESEARCH COUNCIL -MEMBERS FROM A NUMBER OF INSTITUTIONS SELECTED THROUGH UC PRESIDENT'S OFFICE -TECHNICALLY DIVERSE DUE TO NATURE OF ISSUES
MODERATE	-RULES THAT ESTABLISH A REGULATORY LEVEL, STANDARD, OR REQUIREMENT FOR THE PROTECTION OF PUBLIC HEALTH OR ENVIRONMENT	-IMPACTS ARE PRIMARILY SINGLE MEDIA -CONFLUENCE OF SCIENCE AND PUBLIC RISK PERCEPTION -RULES DEVELOPED BASED UPON SUBSTANTIVE BODY OF SCIENTISTS IN AGREEMENT WITH FINDINGS -NEW RISK ASSESSMENT MODELS/APPROACHES	-UC SYSTEM -CSU SYSTEM -SIMILAR INSTITUTION -MEMBERS FROM A NUMBER OF INSTITUTIONS SELECTED THROUGH UC PRESIDENT'S OFFICE -LESS NEED FOR EXTENSIVE TECHNICAL DIVERSITY
LIMITED	-NEW ANALYTICAL/ MEASUREMENT/ MODELING/ DECISION TOOLS	-DATA FOR RECOMMENDING NEW MEASUREMENT METHODS FOR CHEMICAL SPECIES -MODIFICATION OF APPROVED RISK ASSESSMENT MODELS -MODIFIED CRITERIA IN DECISION ANALYSIS TOOLS	-A SMALL GROUP OF TECHNICAL EXPERTS WHO CAN ADDRESS SPECIFIC ISSUE

* THIS MATRIX IS A GUIDE. THE ACTUAL LEVEL OF REVIEW AND TYPE OF PANEL WILL BE CHOSEN BASED ON AN ANALYSIS OF SPECIFIC FACTORS THAT REQUIRE PEER REVIEW.

Senate Bill No. 1320

CHAPTER 295

An act to repeal and add Section 57004 of the Health and Safety Code, and to amend Section 4 of Chapter 1428 of the Statutes of 1985, relating to environmental protection.

[Approved by Governor August 18, 1997. Filed with Secretary of State August 18, 1997.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1320, Sher. Environmental protection.

(1) Existing law required the Director of Environmental Health Hazard Assessment, on or before June 30, 1994, to convene an advisory committee, as prescribed, to conduct a comprehensive review of the policies, methods, and guidelines followed by the boards, departments, and offices within the California Environmental Protection Agency for the identification and assessment of chemical toxicity, as specified.

This bill would delete those provisions and, instead, require the California Environmental Protection Agency, or a board, department, or office within the agency, to enter into an agreement with the National Academy of Sciences, the University of California, the California State University, or any similar institution of higher learning, or any combination of those entities, or with a scientist or group of scientists of comparable stature and qualifications that is recommended by the President of the University of California, to conduct an external scientific peer review of the scientific basis for any rule proposed by any board, department, or office within the agency, and would prescribe procedures for conducting that scientific peer review, as specified.

(2) Existing law requires the Department of Toxic Substances Control to establish specified funding for site operations and maintenance for remedial measures affecting a specified San Gabriel Valley Superfund site, and to deposit sufficient funds to cover the costs of operation and maintenance of carbon absorption treatment systems at the Richwood, Hemlock, and Rurban Homes Mutual Water Companies for 20 years.

This bill would require the department to determine whether it is more economical to provide Richwood residents with a substitute source of water supply than to maintain, operate, or repair a treatment system. If the department determines that a substitute source of water supply is more economical, the bill would allow the expenditure of specified funds to provide Richwood residents with a substitute source of water supply, subject to approval as prescribed.

The people of the State of California do enact as follows:

SECTION 1. Section 57004 of the Health and Safety Code is repealed.

SEC. 2. Section 57004 is added to the Health and Safety Code, to read:

57004. (a) For purposes of this section, the following terms have the following meaning:

(1) "Rule" means either of the following:

(A) A regulation, as defined in subdivision (g) of Section 11342 of the Government Code.

(B) A policy adopted by the State Water Resources Control Board pursuant to the Porter-Cologne Water Quality Control Act (Division 7 (commencing with Section 13000) of the Water Code) that has the effect of a regulation and that is adopted in order to implement or make effective a statute.

(2) "Scientific basis" and "scientific portions" means those foundations of a rule that are premised upon, or derived from, empirical data or other scientific findings, conclusions, or assumptions establishing a regulatory level, standard, or other requirement for the protection of public health or the environment.

(b) The agency, or a board, department, or office within the agency, shall enter into an agreement with the National Academy of Sciences, the University of California, the California State University, or any similar scientific institution of higher learning, any combination of those entities, or with a scientist or group of scientists of comparable stature and qualifications that is recommended by the President of the University of California, to conduct an external scientific peer review of the scientific basis for any rule proposed for adoption by any board, department, or office within the agency. The scientific basis or scientific portion of a rule adopted pursuant to Chapter 6.6 (commencing with Section 25249.5) of Division 20 or Chapter 3.5 (commencing with Section 39650) of Division 26 shall be deemed to have complied with this section if it complies with the peer review processes established pursuant to these statutes.

(c) No person may serve as an external scientific peer reviewer for the scientific portion of a rule if that person participated in the development of the scientific basis or scientific portion of the rule.

(d) No board, department, or office within the agency shall take any action to adopt the final version of a rule unless all of the following conditions are met:

(1) The board, department, or office submits the scientific portions of the proposed rule, along with a statement of the scientific findings, conclusions, and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer review entity for its evaluation.

(2) The external scientific peer review entity, within the timeframe agreed upon by the board, department, or office and the external scientific peer review entity, prepares a written report that contains an evaluation of the scientific basis of the proposed rule. If the external scientific peer review entity finds that the board, department, or office has failed to demonstrate that the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices, the report shall state that finding, and the reasons explaining the finding, within the agreed-upon timeframe. The board, department, or office may accept the finding of the external scientific peer review entity, in whole, or in part, and may revise the scientific portions of the proposed rule accordingly. If the board, department, or office disagrees with any aspect of the finding of the external scientific peer review entity, it shall explain, and include as part of the rulemaking record, its basis for arriving at such a determination in the adoption of the final rule, including the reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices.

(e) The requirements of this section do not apply to any emergency regulation adopted pursuant to subdivision (b) of Section 11346.1 of the Government Code.

(f) Nothing in this section shall be interpreted to, in any way, limit the authority of a board, department, or office within the agency to adopt a rule pursuant to the requirements of the statute that authorizes or requires the adoption of the rule.

SEC. 3. Section 4 of Chapter 1428 of the Statutes of 1985 is amended to read:

Sec. 4. (a) Upon installation of the carbon absorption water treatment systems funded in subdivision (b) of Section 3 of this act, the Department of Toxic Substances Control shall establish, pursuant to Section 25330.5 of the Health and Safety Code, a subaccount for site operation and maintenance for remedial measures affecting the San Gabriel Valley Superfund site, and shall deposit in the subaccount sufficient funds to cover the costs of operation and maintenance of the carbon absorption water treatment systems at the Richwood, Hemlock, and Rurban Homes Mutual Water Companies for 20 years. The funds shall be allocated from the Hazardous Substance Account or the Hazardous Substance Cleanup Fund.

(b) The Department of Toxic Substances Control shall determine whether it is more economical to provide Richwood residents with a substitute source of water supply than to maintain, operate, or repair a treatment system. Notwithstanding any other provision of this act, if the department determines that a substitute source of water supply is more economical, funds appropriated pursuant to subdivision (b) of Section 3 of this act, less the amount, if any, that the department determines it is required to reimburse the

Environmental Protection Agency for the cost of the installation of the water treatment system, may be expended to provide Richwood residents with a substitute source of water supply. The substitute source of water supply shall only be provided by a public water system whose service to the customers of the Richwood Mutual Water Company has been expressly approved by the district engineer of the State Department of Health Services, Drinking Water Field Operations Branch, for the district in which the Richwood Mutual Water Company and the prospective supplier are located. If the Department of Toxic Substances Control expends funds on a substitute source of water supply, no additional funds for the operation and maintenance of the water treatment system at the Richwood Mutual Water Company shall be deposited into the subaccount pursuant to subdivision (a). This subdivision shall not be construed to require the Department of Toxic Substances Control to actually reimburse the Environmental Protection Agency for its share of the cost of the design, purchase, and installation of the water treatment system prior to expending funds to provide Richwood residents with a substitute source of water supply.

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EXECUTIVE DEPARTMENT
STATE OF CALIFORNIA

Executive Order W-137-96

WHEREAS, one of the founding principles of the California Environmental Protection Agency (Cal/EPA) was that regulatory decisions involving assessment of the environmental risk to human health must be based on rigorous and internally consistent science, at the level widely recognized to be the best available in order to ensure that state government regulates effectively and reasonably; and

WHEREAS, the Office of Environmental Health Hazard Assessment within Cal/EPA is charged with providing sound, objective scientific assessment of risks posed by hazardous substances; and

WHEREAS, the California State Legislature enacted SB 1082 (Calderon, 1993), which mandated a study of the risk assessment practices of Cal/EPA programs by a panel of expert scientists, deemed the Risk Assessment Advisory Committee; and

WHEREAS, this panel of distinguished scientists have completed their independent review and published their findings and recommendations in a report titled A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies and Guidelines; and

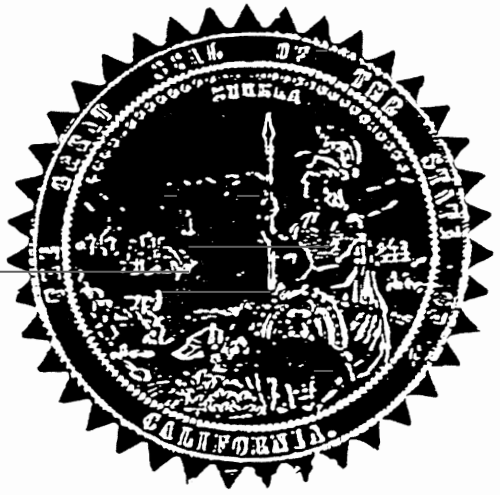
WHEREAS, the focus of the Risk Assessment Advisory Committee review and recommendations is on ensuring that Cal/EPA's human health risk assessment practices are based on sound, up-to-date science, and are objectively and consistently applied, where appropriate, across all of its boards, departments and offices;

NOW, THEREFORE, I, PETE WILSON, Governor of the State of California, by virtue of the power and authority vested in me by the Constitution and statutes of the State of California, do hereby issue this order to become effective immediately:

1. Cal/EPA, including all of its member boards, departments and offices shall evaluate the Committee's report and develop implementation plans for their respective human health risk assessment programs as part of their strategic planning efforts by June 30, 1997. These strategic plans shall establish a program to implement the Committee's recommendations by January 1, 1999.

2. Cal/EPA, including all of its member boards, departments and offices shall take immediate steps to enhance consistency and foster Agency-wide state and federal uniformity in risk assessment methods and practices. Within sixty days, the Secretary for Environmental Protection Agency is hereby directed to convene a task force of Agency and Department heads within state government to identify those boards, departments and offices that assess the toxicity of, exposure to, or risk from chemicals in the environment to human health in order to include them in the uniformity effort and improvement of risk assessment practices as outlined in the Committee's report. Boards, departments and offices identified through this process shall report back to the task force on their implementation plans by June 30, 1997.

3. To implement the results of the review as mandated by SB 1082, I hereby designate, as authorized by Section 11019.6 (a) of the Government Code, Cal/EPA's Office Of Environmental Health Hazard Assessment as the principal state agency for the coordination of procedures, forms and deadlines related to human health risk assessment from chemicals in the environment. All other state agencies shall defer to the principal agency in the performance of their duties in this area, or upon a particular project with respect to procedures, forms, and deadlines, subject to the conditions specified in law. This designation does not apply to the process of any permits pursuant to Division 34 of the Public Resources Code. No part of this order shall be construed to limit the authority of any agency to hold public hearings on any matter within its jurisdiction, and no part of this order shall be construed to authorize any state agency to adopt or implement procedures, forms or deadlines in conflict with those exactly specified in statute or in conflict with the Administrative Procedure Act. Nothing in this order shall be construed to confer upon any state agency decision making authority over substantive matter within another agency's jurisdiction, including any informational and public hearing requirements need to make regulatory and permitting decisions. This order does not apply to any court or office of the judicial branch of government.



IN WITNESS WHEREOF I have hereunto set my hand and caused the Great Seal of the State of California to be affixed this 10th day of December 1996.

Governor of California

ATTEST:

Secretary of State

STATE OF CALIFORNIA

INTERAGENCY AGREEMENT

STD. 13 (REV. 9-89)

APPENDIX E

NUMBER

98-004

THIS AGREEMENT, made and entered into this 15th day of June, 1998 by and between the undersigned State Agencies:

Set forth services, materials, or equipment to be furnished, or work to be performed, and by whom, time for performance including the terms, date of commencement and date of completion, and provision for payment per (1225 and 8752-8752.1 SAM.)

Distribution:
- ☐ Agency providing services
- ☐ Agency receiving services
- ☐ Department of General Services (unless exempt from DGS approval)
- ☐ Controller

This agreement is entered into between the Regents of the University of California (University) and the California Environmental Protection Agency (Agency).

I. University agrees to provide scientific peer review of scientific work on behalf of Agency as part of its rule making and technical management processes as described in Exhibit B, An Overview of the Work Plan.

II. The total amount payable under this Agreement shall not exceed five million dollars ($5,000,000).

III. The term of this Agreement shall be July 1, 1998 through June 30, 2003.

IV. This Agreement is of no force or effect until signed by both parties hereto and approved by the Department of General Services.

V. The following documents are hereby incorporated and made a part of this Agreement.

Exhibit A: Terms of Interagency Master Agreement
Exhibit B: An Overview of the Work Plan
Exhibit C: UC Contract and Grant Offices
Exhibit D: Campus Extramural Funds Accounting Offices
Exhibit E: UC Contract and Grant Offices

(Continued on 0 sheet which is hereby attached and made a part hereof)

NAME OF STATE AGENCY RECEIVING SERVICES	NAME OF STATE AGENCY PROVIDING SERVICES
California Environmental Protection Agency	Regents of the University of California
CALLED ABOVE (SHORT NAME)	CALLED ABOVE (SHORT NAME)
Agency	University
AUTHORIZED SIGNATURE	AUTHORIZED SIGNATURE
☞ E. Farias	☞ David F. Mears 6/1/98
PRINTED NAME AND TITLE OF PERSON SIGNING	PRINTED NAME AND TITLE OF PERSON SIGNING
Enrique Farias Assistant Secretary for Environmental Protection	David F. Mears, Director, Research Admin.
FUND NUMBER AND NAME	FUND NUMBER AND NAME

AMOUNT ENCUMBERED BY THIS DOCUMENT	PROGRAM/CATEGORY (CODE AND TITLE)	FUND TITLE
$5,000,000	Support	MVA
PRIOR AMOUNT ENCUMBERED FOR THIS CONTRACT	(OPTIONAL USE)	
$ 0	Clearing Account	
TOTAL AMOUNT ENCUMBERED TO DATE	ITEM: 0555-001-044 / CHAPTER: BA of 1998 to 2002 / STATUTE: 1998 to 2002 / FISCAL YEAR: 98/9 to 02/03	
$5,000,000	OBJECT OF EXPENDITURE (CODE AND TITLE): 398- 98/9 = #1m; 99/0 #1m; 00/1 #1m; 01/2 #1m; 02/3 #1m.	

I hereby certify upon my own personal knowledge that budgeted funds are available for the period and purpose of the expenditure stated above.

T.B.A. NO. | B.R. NO.

SIGNATURE OF ACCOUNTING OFFICER: ☞ Josephine L. Kontek

DATE: ☞ 5/26/98

Department of General Services Use Only

TERMS OF INTERAGENCY MASTER AGREEMENT

This Interagency Master Agreement ("IMA") is between the State of California Environmental Protection Agency including any of its components ("Agency") and the Regents of the University of California ("University").

1. Non-Exclusivity

This Agreement is non-exclusive. Agency may seek educational, consulting, and/or research services from any and all parties and University may provide such services to any and all parties for the same scope of work or any other scope of work, concurrently or otherwise. "Parties" shall include all individuals, entities, and organizations, whether public or private.

2. Purpose

University shall perform the scope of work set forth in Exhibit B, entitled "An Overview of the Work Plan," attached hereto and incorporated herein ("Work").

3. Funds Obligated

The maximum amount payable by Agency to University for performance of Scientific Peer Review Work shall not exceed $1,000,000 per fiscal year for a total amount not to exceed $5,000,000. For Work performed under individual Task Orders ("TO") issued pursuant to this IMA, Agency agrees to pay University an amount equal to University's direct and 10% indirect costs, as a percentage of modified total direct costs (MTDC), for performance hereunder and approved by Agency in individual TO budgets in accordance with Section 8752 of the State Administrative Manual. Nothing herein shall preclude advance payment pursuant to Government Code Section 11257. Agency is responsible for not issuing TOs which exceed the funds available in this IMA.

4. Term of Agreement

The term of this Agreement shall be from July 1, 1998 through and including June 30, 2003 subject to A) the provisions of Section 3, Funds Obligated, B) the provisions of funding or funding reduction in subsequent fiscal years described in this Section below; and C) Agency's right to termination under Section 5, Termination. No legal liability on the part of the Agency for any payment may arise for performance under this IMA beyond 1998/99 until funds are made available to Agency for performance and until University receives notice of availability, to be confirmed in writing by the Contract Manager.

If funds for any subsequent fiscal year after 1998/99 are reduced or deleted by the Legislature, Agency shall offer a contract amendment. It is mutually understood by both parties that Agency reserves the right to determine which TOs, if any, under this program shall be reduced, and that

Order", which is specifically incorporated herein and made a part thereof by this reference.

C. Requests for services under the terms of this IMA shall be presented in writing by Agency directly to the Contracts and Grants Officers at individual University campuses as identified in Exhibit E, entitled "List of the University of California Contracts and Grants Offices", which is incorporated herein and made a part hereof by this reference. University may decline to provide requested services when such services are inconsistent or incompatible with its mission and purpose as defined in Section 9 of Article IX of the State of California Constitution or when the capability is not otherwise available.

D. No language which supersedes the terms and conditions of this IMA shall be written in the TOs.

8. Subcontracting.

University shall submit for prior written approval by Agency any proposed subcontracting which it desires to enter into for the performance of work under this IMA, except subcontracts with constituent University campuses, or standard employment contracts for personnel to be utilized for work to be carried out under this IMA. Subcontracting which the Agency approves in the proposed TO budget at the time the TO is consummated do not require further Agency approval.

9. Publication

1) Agency shall own all right, title, and interest, including copyright and copyright rights, in and to any deliverable made by University to Agency hereunder. University shall have a non-exclusive, royalty-free right to use, reproduce, and distribute said deliverable(s) for University purposes. University shall own all right, title, and interest, including copyright and copyright rights, to any other material, in whatever form, compiled or used by University in its performance of Work hereunder.

2) After any deliverables have been submitted to Agency, University may, at its own expense or at the expense of the project director or other persons, publish or otherwise utilize reports submitted under terms of this IMA.

3) Agency staff will be given on-site access during reasonable business hours to all data, working papers, facilities, etc., which may be utilized in the performance of a TO.

4) In any publication that results from work supported in full or part under this IMA, the authors shall provide full acknowledgment of the funding source and shall insert and publish the following disclaimer:

"Mention of trade name, proprietary product or specific equipment does not constitute a guaranty or warranty by the California Environmental Protection Agency or any of its Boards, Departments or offices nor does it imply approval to the exclusion of other products that may be

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suitable. The opinions expressed herein represent those of the authors and do not necessarily represent the position of the California Environmental Protection Agency or any of its Boards, Departments, or Offices."

10. Charges

Agency agrees to pay University the charges for services provided to Agency pursuant to this Agreement as agreed in this IMA and as approved by Agency in the TO budget. The TOs shall have a description of the statement of work and results expected of the project.

1) Direct Costs - are those costs that can be identified specifically with a particular project. These include:

   a. Salaries and wages, and fringe benefits rates approved by University. Budgets shall list the categories of personnel, salary rates and time proposed.

   b. Materials and supplies.

   c. Services, e.g., computer time, equipment use.

   d. Travel and per diem in accordance with University travel policy which applies to University employees. Reimbursement for out-of-State travel requires prior written authorization by Agency either by approving such travel in the budget or by letter if such travel is not previously approved in the budget.

   e. Subcontracts

   f. Equipment to be purchased (itemized).

   University may rebudget up to 20% or $10,000, whichever is less, of the total direct costs between existing budget items of the MOU without formal amendment to the TO and without prior Agency approval. Any rebudgeting by University in excess of 20% or $10,000, whichever is less, of the total direct costs between existing budget line items of the TO may be approved by letter signed by Agency Program Manager.

2) Overhead Costs - are those costs incurred for common or joint objectives not readily and specifically identifiable with a particular project.

   In accordance with both Agency and University policy pertaining to the recovery of full costs, overhead costs are included as an allowable cost for performance under this IMA. Agency shall pay overhead of 10% as a percentage of modified total direct costs.

11. Payment

Pursuant to the general authority available in Government Code Sections 11256 through and

including 11263 which provisions are specifically incorporated into this IMA, Agency may make advance payment as follows:

Upon execution of a TO under this IMA, University campus shall submit an advance payment invoice to Agency to advance to University campus the estimated reimbursable cost shown by major costs categories for the first three (3) months of the period of performance of the TO and will reference address of University campus Accounting Office to which payment shall be sent. Prior to the beginning of each quarter thereafter, University will submit an advance payment invoice to Agency to advance the estimated reimbursable costs shown by major cost categories for the ensuring three (3) months. The total amount requested in advance shall not exceed 90 percent of the total allowable costs in the subject TO. The remaining 10 percent shall be paid only after receipt of a satisfactory final report.

Within sixty (60) days of the end of each quarter, University will submit to Agency a statement of total actual expenditures by major cost categories incurred during the preceding quarter. The fourth quarterly statement of the performance period will serve as the final fiscal report and is due ninety (90) days after the end of the performance period. Any funds advanced in excess of actual expenditures will be refunded by University campus.

Agency shall accept University statement of expenditures without back-up source documentation. Source documentation is retained in official University financial records and may be inspected on site at reasonable times in accordance with Clause 15 below. It is agreed between the parties hereto that upon completion of the services hereunder, the actual cost of rendering said service shall be computed in accordance with the provisions of Section 8752 of the State Administrative Manual and said payment adjusted in accordance with the provisions of Article 1, Chapter 3, Part 1, Division 3, Title 2, Government Code.

12. Invoices

Invoices shall reference this IMA and the applicable TO, and the University campus Accounting Office address to which payment shall be sent, and include direct expenses and indirect costs consistent with the elements in the budget approved by Agency.

Submit invoices to:

Samuel Banks
California Environmental Protection Agency
555 Capitol Mall, Suite 525
Sacramento, CA 95814

Agency agrees to make payment on all invoices to The Regents of the University of California in accordance with the State Prompt Payment Act and mail payment to the appropriate University campus Accounting Office as designated in the TO.

The addresses of all University campus Accounting Offices are listed in Exhibit D, incorporated herein and made a part hereof by this reference.

13. Format

Agency shall accept University computer generated invoices without back-up source documentation. Source documentation is retained in official University financial records and may be inspected on site at reasonable times in accordance with Clause 15 below.

14. Property

Equipment charged as a direct cost of a TO shall be the property of Agency. At the completion or termination of each TO, University will report the purchased equipment to Agency.

Agency will provide disposition instructions within 120 days after receipt of the equipment report from University. If disposition instructions are not provided within 120 days, title to equipment shall automatically rest in the University with no further accountability to Agency.

15. Audit

University agrees that this IMA is subject to examination and audit by the State Auditor for a period of three years after final payment under said IMA.

16. Patents and Rights in Data

A. Confidentiality. Neither party shall furnish any information to the other party in connection with this Agreement that is considered enabling, confidential, or proprietary by it or by any third parties, without a prior, separate written agreement between the parties that allows such information to be furnished.

B. Patent Rights. All rights to any patentable inventions or discoveries conceived or reduced to practice in the performance of the work conducted under this IMA and its TOs shall belong to University.

C. Rights in Data. All proposals, protocols, information, results, and computer programs (collectively hereafter called "Data") developed for or in the course of the performance of the work under this IMA and its TOs, including the exclusive right to obtain copyright and control the exclusive copyrights shall belong to University. University shall grant the State a non-exclusive, royalty-free right in Data to practice or have practiced for or on behalf of the State of California.

17. Amendment

The terms of this IMA may be amended in writing as mutually agreed by the contract managers or their delegates.

AN OVERVIEW OF THE WORK PLAN

The areas University and Agency are focusing on include:

1. Scientific Peer Review by University of scientific work performed by or on behalf of Agency as part of its rule-making or technical management processes.

2. Partnering to ensure that the most appropriate experts are identified, screened, and selected to address scientific underpinnings of proposed State environmental initiatives to address California's environmental issues.

3. University Office of the President will develop mechanisms for collaborative efforts to:

   A. Compile a continuously updated "skills bank" of University faculty and staff that identifies people having specialized knowledge and expertise who are willing to serve as peer reviewers for Agency.

   B. Develop and implement mechanisms for identifying, screening and approving scientific experts from other institutions for peer review and appropriate Agency work products. It is anticipated that the President's Office will receive input from both its own faculty and Agency and its Boards, Department, and Offices. Agency may submit to the Office of the President for its consideration and recommendation the names and affiliations of three potential reviewers for each task order. The Office of the President, at its discretion may select from the three candidates, or select any other qualified peer reviewer to conduct the work described in the task order. From time-to-time, this could include selection and funding of qualified peer reviewers from other highly regarded national institutions.

4. After receiving a recommendation from the U.C. President's Office for an appropriate peer reviewer, Agency will request work directly from that reviewer's campus via individual task orders.

EXHIBIT C
INTERAGENCY AGREEMENT NO. 98-004
AGENCY/UNIVERSITY

TASK ORDER

1. This Task Order (TO) is entered into pursuant to the provisions of Interagency Master Agreement (IMA) No., dated _____ between the California Environmental Protection Agency ("Agency") and The Regents of the University of California, _____ campus ("University"). This TO implements, is made part of the IMA and incorporates the IMA provisions applicable to TOs.

2. University shall provide Agency with the following services:
[Describe Scope of Peer Review Work here.]

3. University Project Manager is:
University campus Contract and Grant Officer is:

4. [Specify the effective date of the TO, the period of performance and schedule for submission of reports if this is not provided under 2. Scope of Work. The period of performance must not extend beyond the termination date of the IMA.]

5. [Specify the amount to be paid under this TO.]

6. [Incorporate the budget mutually agreed to in accordance with the major cost categories listed in IMA Article 10.]

7. This TO may be terminated by either part upon thirty (30) days advance written notice.

8. In order to ensure a multi-media focus, and more cost-effective use of available funds, Peer Review Task Orders from Boards and Departments will be co-signed by the Office of the Secretary. The selected reviewer will accept only co-signed Task Orders.

9. Address of the University campus Accounting Office to which payment shall be sent is:

Department Authorized Representative:	University Campus Contract and Grant Officer
Signature	Signature
Name and title printed Date	Name and title printed Date

Agency Authorized Representatives:

Special Assistant for Health Sciences

Signature

Name and title printed
Date

Assistant for Fiscal and Administrative Programs

Signature

Name and title printed
Date

EXHIBIT D

Campus Extramural Funds Accounting Offices

Contract and Grant Accounting
481 University Hall
University of California
Berkeley, CA. 94720

Accounting Office
University Services Building
University of California
Davis, CA. 95616

Contract and Grant Accounting
Accounting Office
390 Berkeley Place
University of California
Irvine, CA. 92717-1050

Extramural Funds Management
911 Broxton Avenue
University of California
Los Angeles, CA. 90024-1400

Extramural Funds Accounting
Accounting Office
University of California
Torrey Pines Center N 0954
La Jolla, CA. 92093

Accounting Office
1650 Spruce Street, 3rd fl.
University of California
Riverside, CA. 92521

Extramural Funds and Financial Systems
Box 0812, MCB 425
University of California
San Francisco, CA. 94143

Extramural Funds Accounting
Accounting and Financial Services
4219 Cheadle Hall, 4th fl.
University of California
Santa Barbara, CA. 93106-2040

Extramural Funds
364C Applied Science Building
University of California
Santa Cruz, CA. 95064

1/98

EXHIBIT E

UC CONTRACT AND GRANT OFFICES

Joyce Freedman, Director
Sponsored Projects Office
336 Sproul Hall
University of California
Berkeley, CA 94720
Phone: (510) 642-8110
FAX: (510) 642-8236

Ahmad Hakim-Elahi
Office of Vice Chancellor - Research
410 Mrak Hall
University of California
Davis, CA 95616
Phone: (916) 752-7630
FAX: (916) 752-8671

Christina Hansen, Director
Office of Contract & Gran
115 Administration Buildin
University of California
Irvine, CA 92717
Phone: (714) 856-5677
FAX: (714) 725-2094

Dorothy Crocker, Director
Office of Research Administration
1400 Ueberroth Building
University of California
Los Angeles, CA 90024
Phone: (310) 825-1431
FAX: (310) 206-4996

Hannah Petzenbaum, Director
Office of Research Affairs
1126 Library South
University of California
Riverside, CA 92521
Phone: (909) 787-5535
FAX: (909) 787-4483

Linda Dale, Director
Office of Contract & Gran
0934, UC San Diego
9500 Gilman Drive
La Jolla, CA 92093-0934
Phone: (619) 534-3333
FAX: (619) 534-0280

Nancy Wilson, Manager
Contracts and Grants
Scripps Institution of Oceanography
UC San Diego, 0210
La Jolla, CA 92093-0210
Phone: (619) 534-4570
FAX: (619) 534-5306

John Klimek, Manager
Office of Research Affairs
3333 California Street, Suite 11
University of California
San Francisco, CA 94143-0962
Phone: (415) 476-2977
FAX: (415) 476-8158

Pamela Webb, Manager
Sponsored Projects
3227 Cheadle Hall
University of California
Santa Barbara, CA 93106
Phone: (805) 893-4036
FAX: (805) 893-2611

Bill Clark, Manager
Contracts and Grants Office
399C Applied Sciences Building
University of California
Santa Cruz, CA 95064
Phone: (408) 459-2778
FAX: (408) 459-4989

Carol Berman
Contracts and Grants Coordinator
ANR, Office of the President
300 Lakeside Drive, 6th Floor
Oakland, CA 94612-3550
Phone: (510) 987-0050
FAX: (510) 763-6436

David F. Mears, Director
RAO, Office of the President
University of California
1111 Franklin St., 5th fl.
Oakland, CA 94607-5200
Phone: (510) 987-9838
FAX: (510) 835-3705

UC LAB AND CAMPUS CONTRACTS AND GRANTS OFFICES (1/98)